TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
09714		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/019694	22.12.2004	26.12.2003

International Patent Classification (IPC) or national classification and IPC

C12N15/09, C07K16/18, C07K16/42, G01N33/53, G01N33/543, C12P21/08

Applicant

Dainippon Sumitomo Pharma Co., Ltd.

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/019694

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/019694

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-18	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-18	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: Int. Archs. Allergy Appl. Immun., 1985, 77 (4), pages 438 to 444

Newly cited document:

Document 2: Int. Archs. Allergy Immunol., 1993, 102 (2), pages 176 to 184

The inventions set forth in claims 1 to 18 do not involve an inventive step in the light of document 1 cited in the international search report and newly cited document 2.

Document 1 indicates that a fraction containing a large quantity of IgE is prepared from the blood serum of a guinea pig immunized with antigens in order to prepare an antibody to guinea pig IgE.

Document 2 indicates that IgE that does not contain other immunoglobulin is isolated from canine blood serum, and a method for doing so.

It would be easy for a person skilled in the art to conceive of employing the method of refining IgE set forth in document 2 in the preparation of a fraction containing a large quantity of guinea pig IgE set forth in document 1 in order to obtain IgE with a high degree of purity, and to use the antibodies to the refined

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

guinea pig IgE thus obtained in different types of measurements of immunity. Moreover, with regard to the effect of the invention of this application, the present invention does not offer a marked effect in the light of the invention set forth in documents 1 and 2 and the protein refining methods which were known at the time of filing of this application.

In the response to the written opinion, the applicant claims that the guinea pig IgE obtained in the embodiment of this application contains extremely high concentrations of IgE with maintained bioactivity compared to the canine IgE obtained using the refining method set forth in document 2.

However, there is no specification by refining method in claims 1 to 18, and the quantitative disclosure of bioactivity and bioactive properties only specifies the cross reaction rate between guinea pig IgG and IgM in claim 9, and there is no disclosure of the bonding capacity of guinea pig IgE mast cells and the bonding capacity with antigens.

That being the case, claims 1 to 18 broadly contain, aside from the guinea pig IgE having excellent bioactivity such as that obtained by the embodiment of this application, and its related inventions, guinea pig IgE having low bioactivity and its related inventions.

Therefore, viewed overall, it would be easy for a person skilled in the art to conceive of the inventions set forth in claims 1 to 18 in the light of documents 1 and 2.